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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/259,758	03/01/1999	SUSAN K. BROWN-SKROBOT	VTN-0388	5657

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EXAMINER	
CHORBAJI, MONZER R	

ART UNIT	PAPER NUMBER
1744	

DATE MAILED: 05/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/259,758	BROWN-SKROBOT ET AL.	
	Examiner	Art Unit	
	MONZER R CHORBAJI	1744	

-- The MAILING DATE of this communication appears on th cover she t with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 March 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-13,18-30,33-41 and 51-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-13,18-30,33-41 and 51-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☒ Interview Summary (PTO-413) Paper No(s). *24* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

This non-final office action after RCE is in response to the amendment received on 03/06/20

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over Briggs (WO 97/35624).

With regard to claim 51, Briggs discloses a process and an apparatus for sterilizing contact lens (page 4, lines 21-23 and page 5, lines 1-6), which includes the following concepts: subjecting contact lens (8A and 8B) to UV radiation in the range of 240 to 280 NM (page 3, lines 10-12), and the container is transmissive to at least 50% of UV (figure A and page 5, lines 5-6). In addition, Briggs discloses a contact lens container (figure A, 8A and 8B) subjected to UV radiation in substantially all directions (page 2, lines 14-23 and page 5, lines 5-6). Briggs fails to explicitly state that the contact lens container is hermetically sealed. However, Since Briggs sterilize contact lens, it is credible that Briggs's container is hermetically sealed in order to prevent microorganisms from entering the container and contaminating the sterilized contact lens.

5. Claims 7-10, 12, 18-30, 35-41, 55, and 57-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Briggs (WO 97/35624) in view of Clark et al (U.S.P.N. 5,786,598).

With respect to claims 7, 18, 20, 35, and 55, Briggs fails to disclose the following concepts: having more than one radiation source, contact lens blocks at least 50% of the UV radiation, minimum total energy range for UV, forming a contact lens, placing contact lens in a container, and moving the container into a light-tight apparatus. Clark et al teaches the following: more than 1 radiation source (col.6, line 26), the contact lens blocks at least 50% of the UV radiation (col.4, lines 16-17, since the contact lens

transmits more than about 1% which is equivalent to blocking UV radiation to at least 50%) such that the range of UV radiation is in the range 240-280 NM (col.3, line 3), subjecting a medical device (col.1, lines 13-15) to UV radiation (col.3, lines 60-62) in the range of 240-280 NM (col.3, lines 60-63) using energy value at least 18 mj/cm^2 or 30 mj/cm^2 or 36 mj/cm^2 (col.8, lines 10-12), forming and placing a contact lens (col.7, lines 61-67 and col.8, lines 1-5) in a container, moving the container into an apparatus (col.7, lines 1-3), which is light-tight (col.8, lines 38-39), and Clark's container is subjected within a light-tight apparatus (col.8, lines 38-39 and col.7, lines 1-3). Thus, it would have been obvious to one having ordinary skill in the art to utilize the teachings of Clark et al into Briggs in order to design a sterilizing apparatus, which functions in a continuous mode (col5, lines 62-67 and col.6, lines 1-5).

With regard to claims 8-10, Clark discloses the following: radiation sources pulse substantially simultaneously (col.10, lines 35-37, since the reference establishes multiple flash lamps using time ranges which encompass all the time values of the claims), and flash lamps comprises a reflector and a lamp (figure 1, 22) wherein the fluence of each is at the focal plane of reflector (figure 1, 22:20).

With regard to claim 12, Clark teaches that the radiation is delivered by flash lamps in at most three pulses (col.9, lines 62-67 and col.10, lines 33-37).

With regard to claims 19 and 21-30, Clark discloses the following: container comprises an aqueous solution (col.8, line 4), various time ranges for applying the radiation such that all the values in the claims fall into (col.8, lines 11-12), modifying radiation from a radiation source to eliminate wavelengths which would damage contact

lens (col.3, line 36, line 38, and col.4, lines 55-57) such that contact lens are sterilized (col.6, lines 63-65 and col.7, lines 1-3), and container comprises a non-preserved aqueous solution (col.1, lines 10-13).

With regard to claims 36-41, Clark teaches a process and an apparatus for sterilizing contact lens (col.1, lines 7-20 and col.4, lines 55-57) including the following: the use of packages or containers is disclosed made of thermoplastics (col.3, line 48 and col.1, lines 29-30); at least one flash lamp containing a rare gas as a luminous component (col.10, lines 20-25), the contact lens blocks at least 50% of the UV radiation (col.4, lines 16-17, since the contact lens transmits more than about 1% which is equivalent to blocking UV radiation to at least 50%), container comprises an aqueous solution (col.8, line 4), and radiation sources pulse substantially simultaneously (col.10, lines 35-37, since the reference establishes multiple flash lamps using time ranges which encompass all the time values of the claims).

With respect to claims 57-60, Clark et al teaches the following: at least one reflector directs radiation from each radiation source to a treatment area (figure 1, 18:22); treatment area is located at the focal plane of reflector (figure 8, 18:22 and the unlabeled rays). In addition; Clark et al teaches of a capacitance and a potential (col.10, lines 1-8), however; Clark et al does not provide specific values for capacitance and for potential. Since the claims are trying to exactly accomplish what Clark et al teaches then it is intrinsic in the apparatus of Clark et al to encompass the same values for capacitance and a potential. Furthermore, Clark et al discloses the use of reflectors with enhanced reflection (col.6, lines 42-44); and the reflector minimizes the non-ultraviolet

radiation reaching the medical device (col.6, lines 45-48). In addition, see col.8, lines 11-15 for various energy values.

6. Claims 2-6, 11, and 52-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Briggs (WO 97/35624) in views of Clark et al (U.S.P.N. 5,786,598) and further in view of Matner et al (U.S.P.N. 5,252,484) and Shalaby et al (U.S.P.N. 5,422,068).

With respect to claims 2-6, 11, and 52-54 Briggs fails to disclose the following: sterility assurance level, UV energy values, pulse time intervals, D-values for Bacillus Stearothermophilus, ATCC 7953, and how to determine such a value. With respect to claims 2-6 and 11, Clark teaches the following: a sterility assurance level of at 10^-6 (abstract, line 21), all the energy values in the claims fall within the teaching of Clark et al energy value range (col.8, lines 10-12), which contains a specific low range value and a specific high range value, the application of UV radiation to spores (col.9, lines 50-53), the usage of at least one pulsed radiation source (col.6, line 26 and col.3, lines 51-56), various time ranges for applying the radiation which all the values in the claim fall into (col.8, lines 12-19), and pulsed radiation source in at most three pulses (col.9, lines 62-67 and col.10, lines 33-37). However, with regard to claims 52-54, Clark fails to disclose D value for Bacillus Stearothermophilus, ATCC 7953 and how to determine such a value. With respect to claims 52-54, Matner teaches a method for determining the efficacy of a sterilization cycle (col.1, lines 7-8) wherein it is known to use Bacillus Stearothermophilus ATCC 7935 to verify how efficient a sterilization cycle is (col.2, lines 35-39). Matner fails to teach D values specific for Bacillus Stearothermophilus, ATCC

7953. With regard to claims 52-54, Shalaby teaches the concept of D-value and its importance to sterility assurance level is explained (col.3, lines 28-65). Also the D-values of Bacillus Stearothermophilus are shown (columns 6-11). Furthermore; Shalaby teaches of known mathematical relationship between transmissivity, and D-values (col.3, lines 46-57). It would have been obvious to one having ordinary skill in the art to modify Briggs's process by applying UV radiation to Bacillus Stearothermophilus ATCC 7935 in order to determine the sterilizing efficacy since such organisms are recognized as the most resistant form of microbial life (Matner, col.5, lines 53-60 and col.6, lines 3-4).

7. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Briggs (WO 97/35624) in view of Dunn et al (U.S.P.N. 4,910,942).

With regard to claim 13, Briggs fails to disclose the use of laser. However, Dunn teaches of a method for sterilizing packaging of medical devices (col.1, lines 17-21) wherein the usage of laser radiation is known (col.2, lines 17-22). It would have been obvious to one having ordinary skill in the art to modify Briggs's process to include a laser source in order to sterilize light-transmissive containers (Dunn, col.2, lines 14-15 and lines 18-19).

8. Claims 33-34 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Briggs (WO 97/35624) in view of Clark et al (U.S.P.N. 5,786,598).

With respect to claim 33, Briggs discloses a container including a lid and a bowl (2 and 4) such that the lid and the bowl are transmissive to at least 50% of UV radiation in the range of 240 to 280 NM in substantially all directions. However, Briggs fails to

disclose that the lid and bowl consist essentially of thermoplastics. Clark's container (50) consists essentially of thermoplastics (col.7, lines 3-6). It would have been obvious to one having ordinary skill in the art to modify Briggs's container by designing a lid and a bowl made up of thermoplastics since such material has superior moisture vapor barrier characteristics (Clark et al, col.7, lines 7-10).

With respect to claims 34 and 56, Clark et al discloses at least one flash lamp containing a rare gas as a luminous component (col.10, lines 20-25), and the apparatus is light tight (col.8, lines 38-39).

9. Claims 7-10, 12, 18-30, 35-41, 51, and 55, 57-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Briggs (WO 97/35624) in view of Clark et al (U.S.P.N. 5,786,598).

With respect to claim 51, Briggs teaches a process and an apparatus for sterilizing contact lens (page 4, lines 21-23 and page 5, lines 1-6), which includes the following concepts: subjecting contact lens (8A and 8B) to UV in the range of 240 to 280 NM (page 3, lines 10-12), and the container is transmissive to at least 50% of UV (figure A and page 5, lines 5-6). In addition, Briggs discloses a contact lens container (figure A, 8A and 8B) subjected to UV radiation in substantially all directions (page 2, lines 14-23 and page 5, lines 5-6). However, Briggs fails to teach a hermetically sealed container. Clark et al discloses having contact lens in a hermitically sealed container (col.8, line 33). Thus, it would have been obvious to one having ordinary skill in the art to modify Briggs's contact lens container by designing a container, which is hermetically sealed in order to maintain contact lenses in a sterilized condition.

With regard to claims 7-10, Clark discloses the following: more than 1 radiation source (col.6, line 26), radiation sources pulse substantially simultaneously (col.10, lines 35-37, since the reference establishes multiple flash lamps using time ranges which encompass all the time values of the claims), and flash lamps comprises a reflector and a lamp (figure 1, 22) wherein the fluence of each is at the focal plane of reflector (figure 1, 22:20).

With regard to claim 12, Clark teaches that the radiation is delivered by flash lamps in at most three pulses (col.9, lines 62-67 and col.10, lines 33-37).

With regard to claims 18-30, Clark discloses the following: the contact lens blocks at least 50% of the UV radiation (col.4, lines 16-17, since the contact lens transmits more than about 1% which is equivalent to blocking UV radiation to at least 50%) such that the range of UV radiation is in the range 240-280 NM (col.3, line 3), container comprises an aqueous solution (col.8, line 4), subjecting a medical device (col.1, lines 13-15) to UV radiation (col.3, lines 60-62) in the range of 240-280 NM (col.3, lines 60-63) using energy value at least 18 mj/cm^2 or 30 mj/cm^2 or 36 mj/cm^2 (col.8, lines 10-12), various time ranges for applying the radiation such that all the values in the claims fall into (col.8, lines 11-12), modifying radiation from a radiation source to eliminate wavelengths which would damage contact lens (col.3, line 36, line 38, and col.4, lines 55-57) such that contact lens are sterilized (col.6, lines 63-65 and col.7, lines 1-3), and container comprises a non-preserved aqueous solution (col.1, lines 10-13).

With regard to claims 35-41, Clark teaches a process and an apparatus for sterilizing contact lens (col.1, lines 7-20 and col.4, lines 55-57) including the following: forming and placing a contact lens (col.7, lines 61-67 and col.8, lines 1-5) in a container, moving the container into an apparatus (col.7, lines 1-3), which is light-tight (col.8, lines 38-39) the use of packages or containers is disclosed made of thermoplastics (col.3, line 48 and col.1, lines 29-30); at least one flash lamp containing a rare gas as a luminous component (col.10, lines 20-25), the contact lens blocks at least 50% of the UV radiation (col.4, lines 16-17, since the contact lens transmits more than about 1% which is equivalent to blocking UV radiation to at least 50%), container comprises an aqueous solution (col.8, line 4), and radiation sources pulse substantially simultaneously (col.10, lines 35-37, since the reference establishes multiple flash lamps using time ranges which encompass all the time values of the claims).

With respect to claim 55, Clark's container is subjected within a light-tight apparatus (col.8, lines 38-39 and col.7, lines 1-3).

With respect to claims 57-60, Clark et al teaches the following: at least one reflector directs radiation from each radiation source to a treatment area (figure 1, 18:22); treatment area is located at the focal plane of reflector (figure 8, 18:22 and the unlabeled rays). In addition; Clark et al teaches of a capacitance and a potential (col.10, lines 1-8), however; Clark et al does not provide specific values for capacitance and for potential. Since the claims are trying to exactly accomplish what Clark et al teaches then it is intrinsic in the apparatus of Clark et al to encompass the same values for capacitance and a potential. Furthermore, Clark et al discloses the use of reflectors with

enhanced reflection (col.6, lines 42-44); and the reflector minimizes the non-ultraviolet radiation reaching the medical device (col.6, lines 45-48). In addition, see col.8, lines 11-15 for various energy values.

10. Claims 2-6, 11, and 52-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Briggs (WO 97/35624) in views of Clark et al (U.S.P.N. 5,786,598) and further in view of Matner et al (U.S.P.N. 5,252,484) and Shalaby et al (U.S.P.N. 5,422,068).

With respect to claims 2-6, 11, and 52-54 Briggs fails to disclose the following: sterility assurance level, UV energy values, pulse time intervals, D-values for Bacillus Stearothermophilus, ATCC 7953, and how to determine such a value. With respect to claims 2-6 and 11, Clark teaches the following: a sterility assurance level of at 10^-6 (abstract, line 21), all the energy values in the claims fall within the teaching of Clark et al energy value range (col.8, lines 10-12), which contains a specific low range value and a specific high range value, the application of UV radiation to spores (col.9, lines 50-53), the usage of at least one pulsed radiation source (col.6, line 26 and col.3, lines 51-56), various time ranges for applying the radiation which all the values in the claim fall into (col.8, lines 12-19), and pulsed radiation source in at most three pulses (col.9, lines 62-67 and col.10, lines 33-37). However, with regard to claims 52-54, Clark fails to disclose D value for Bacillus Stearothermophilus, ATCC 7953 and how to determine such a value. With respect to claims 52-54, Matner teaches a method for determining the efficacy of a sterilization cycle (col.1, lines 7-8) wherein it is known to use Bacillus Stearothermophilus ATCC 7935 to verify how efficient a sterilization cycle is (col.2, lines

35-39). Matner fails to teach D values specific for Bacillus Stearothermophilus, ATCC 7953. With regard to claims 52-54, Shalaby teaches the concept of D-value and its importance to sterility assurance level is explained (col.3, lines 28-65). Also the D-values of Bacillus Stearothermophilus are shown (columns 6-11). Furthermore; Shalaby teaches of known mathematical relationship between transmissivity, and D-values (col.3, lines 46-57). It would have been obvious to one having ordinary skill in the art to modify Briggs's process by applying UV radiation to Bacillus Stearothermophilus ATCC 7935 in order to determine the sterilizing efficacy since such organisms are recognized as the most resistant form of microbial life (Matner, col.5, lines 53-60 and col.6, lines 3-4).

11. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Briggs (WO 97/35624) in view of Clark et al (U.S.P.N. 5,786,598) and further in view of Dunn et al (U.S.P.N. 4,910,942).

With regard to claim 13, both Briggs and Clark fail to disclose the use of laser. However, Dunn teaches of a method for sterilizing packaging of medical devices (col.1, lines 17-21) wherein the usage of laser radiation is known (col.2, lines 17-22). It would have been obvious to one having ordinary skill in the art to modify Briggs's process to include a laser source in order to sterilize light-transmissive containers (Dunn, col.2, lines 14-15 and lines 18-19).

12. Claims 33-34 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Briggs (WO 97/35624) in view of Clark et al (U.S.P.N. 5,786,598).

With respect to claim 33, Briggs discloses a container including a lid and a bowl (2 and 4) such that the lid and the bowl are transmissive to at least 50% of UV radiation in the range of 240 to 280 NM in substantially all directions. However, Briggs fails to disclose that the lid and bowl consist essentially of thermoplastics. Clark's container (50) consists essentially of thermoplastics (col.7, lines 3-6). It would have been obvious to one having ordinary skill in the art to modify Briggs's container by designing a lid and a bowl made up of thermoplastics since such material has superior moisture vapor barrier characteristics (Clark et al, col.7, lines 7-10).

With respect to claims 34 and 56, Clark et al discloses at least one flash lamp containing a rare gas as a luminous component (col.10, lines 20-25), and the apparatus is light tight (col.8, lines 38-39).

Response to Arguments

13. Applicant's arguments with respect to claims 2-13, 18-30, 33-41, and 51-60 have been considered but are moot in view of the new ground(s) of rejection.

On page 2 of the response, applicant argues, "Clark does not teach nor suggest that the contact lens container can or should be transmissive to radiation in substantially all directions". The Briggs reference is used to show a contact lens container, which is transmissive to UV light, and also is subjected to UV radiation in substantially all directions (Figure A, and page 5, lines 5-6).

On page 4 of the response, applicant argues, "col.10, lines 35-37 do not mention radiation sources pulsing simultaneously". The examiner also, cited col.6, line 26 that teaches multiple UV lamps, such that col.10, lines 35-37 teaches multiple flashes over a

very short time interval. Thus, Clark et al teaches multiple UV lamps flashing at different very short time intervals, which result in simultaneous pulsing. In addition, figure 1 shows radiation sources (arrows) simultaneously pulsing from substantially all directions onto a container.

On page 4 of the response, applicant argues, "claim 10 claims a specific minimum amount of UV radiation that must reach the focal plane, which is not taught or suggested by the large ranges of broad spectrum radiation that is disclosed by Clark". The minimum amount of UV radiation that must reach the focal plane is 45 mJ/cm^2 which, falls within the disclosed fluence range in Clark et al (col.8, lines 10-12). Further, Clark et al provides specific values within this range that one ordinary skill in the art would understand to choose any fluence value depending on the kind of device and materials to be treated with the UV radiation.

On page 4 of the response, applicant argues, "The term focal plane is not even mentioned in Clark". On page 15, lines 23-31 of the specification, applicant teaches that reflectors inherently have focal planes. Clark et al discloses reflectors (22) that have focal planes.

On page 5 of the response, applicant argues, "col.3, line 63 discloses a range of 180 to 300 NM radiation. That is the most narrow range of radiation disclosed by Clark. Applicant specifies the energy requirements and transmissivity requirements are for a more narrow range (240-280 NM) of the radiation to achieve sterility of the product. Clark et al in clo.3, lines 60-63 also provide other ranges such that one ordinary skill in the art would understand to choose the proper transmissivity and energy values

depending on the type of device and material to be treated with the UV radiation. In addition, Briggs discloses an energy value of about 260 NM (page 3, lines 10-12) that is known for its germicidal properties.

On page 5 of the response, applicant argues, "it is not clear if those amounts of energy are for the entire spectrum of radiation produced by the apparatus or for the specified ranges of radiation, and if it is for the entire spectrum, it does not state what portion of the entire spectrum is the radiation in the range of 240-260 NM". The various amounts of energy values correspond with the ranges of radiation as disclosed in Clark et al (col.8, lines 9-16). In addition, the claims do not recite the limitation regarding what portion of the entire spectrum is the radiation in the range of 240-260 NM.

On page 5 of the response, applicant argues, "Applicants disagree that Clark teaches or suggests a light-tight apparatus". Clark et al teaches that the apparatus can include either a tunnel or a sterilizing chamber (col.8, lines 38-40). The word chamber means a closed structure with a door or doors for closure. Thus, Clark et al sterilizing chamber is a light-tight structure where the radiation is kept within the chamber. Figure 1 refers to a tunnel, which has both ends open.

On page 6 of the response, applicant argues, "Clark does not teach nor suggest Applicant's capacitance range, and it is not intrinsic in the apparatus of Clark, because Clark is not trying to accomplish the same process". Both Clark et al and the applicants disclose a process for sterilizing contact lens. Clark et al teaches that the apparatus includes a capacitance (col.10, lines 2-4) in order for the apparatus to function without disclosing specific capacitance range. As a result, it is credible that Clark et al

capacitance has a range value such that one ordinary skill in the art would understand choosing a capacitance range depends on the kind of device and materials to be sterilized with the UV radiation.

On page 7 of the response, applicant argues, "the D-values for Applicant's process were not disclosed, taught, nor suggested, nor is it disclosed that Bacillus Stearothermophilus would be the most difficult microorganism to kill in Applicant's process". First, Matner et al teaches that Bacillus Stearothermophilus is known to be used as a sterilization monitor (col.2, lines 35-29) and it is the most difficult microorganism to kill (col.5, lines 53-64). Also, Matner et al mentions that Bacillus Stearothermophilus is used to monitor sterilization process utilizing radiation. Furthermore, Shalaby et al discloses D-values for Bacillus Stearothermophilus in table I of example 2. See the definition of D value in col.3, lines 51-57.

On page 8 of the response, applicant argues, "Dunn does not teach a method of sterilizing packaging for medical devices using laser radiation". Dunn's title does disclose a method for sterilizing packaging of medical devices such that laser is known to sterilize packages (col.2, lines 19-22).

Conclusion

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R CHORBAJI whose telephone number is (703) 305-3605. The examiner can normally be reached on M-F 8:30-5:00.

15. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ROBERT J WARDEN can be reached on (703) 308-2920. The fax phone

numbers for the organization where this application or proceeding is assigned are (703) 305-3599 for regular communications and (703) 305-7719 for After Final communications.

16. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Monzer R. Chorbaji MRC
Patent Examiner
AU 1744
May 14, 2003

Robert J. Warden, Sr.
ROBERT J. WARDEN, SR.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1700